

CLAIMS

What is claimed is:

1. A method for accelerating a qualification test for a ceramic component intended for implantation in living body tissue, comprising the steps of:
 - selecting the ceramic component having a plurality of preselected physical characteristics, said characteristics including an initial monoclinic phase content;
 - exposing the ceramic component to an aqueous milieu at a preselected elevated temperature for a preselected time period;
 - removing the ceramic component from the aqueous milieu and measuring its post-exposure monoclinic phase content;
 - measuring a difference between the initial and post-exposure monoclinic phase content; and
 - qualifying the ceramic component for implant if the difference between the initial and post-exposure monoclinic phase content is less than a preselected value.
2. The method for accelerating a qualification test according to claim 1, wherein said step of exposing the ceramic component to an aqueous milieu is performed in steam.
3. The method for accelerating a qualification test according to claim 1, wherein said step of exposing the ceramic component to an aqueous milieu is performed at the preselected elevated temperature of 127°C.
4. The method for accelerating a qualification test according to claim 1, wherein said step of exposing the ceramic component to an aqueous milieu is performed for the preselected time of six hours.

5. The method for accelerating a qualification test according to claim 1, wherein said step of qualifying the ceramic component comprises selecting 2.1% as the preselected value.

6. The method for accelerating a qualification test according to claim 1, wherein said step of selecting the ceramic component comprises selecting an actual component to be implanted.

7. The method for accelerating a qualification test according to claim 1, wherein said step of selecting the ceramic component comprises selecting a witness sample.

8. The method for accelerating a qualification test according to claim 1, wherein said step of selecting the ceramic component comprises selecting an yttria tetragonal zirconium oxide polycrystal ceramic.

9. The method for accelerating a qualification test according to claim 1, wherein said step of selecting the ceramic component comprises selecting a stabilized zirconia ceramic.

10. The method for accelerating a qualification test according to claim 1, wherein said step of selecting the ceramic component comprises selecting a zirconia ceramic that is stabilized with one or more additives of yttria, ceria, calcia, hafnia or magnesia.

11. The method for accelerating a qualification test according to claim 1, wherein said step of selecting the ceramic component comprises selecting an yttria stabilized zirconia.

12. The method for accelerating a qualification test according to claim 1, further comprising the step of qualifying the ceramic component for implant by examining the ceramic acoustically.

13. The method for accelerating a qualification test according to claim 12, wherein said step of examining by acoustic test is rejecting said ceramic component if a flaw greater than three microns is detected.

14. The method for accelerating a qualification test according to claim 1, further comprising the step of conducting a proof test to 800 MPa in flexure.

15. A method for accepting a ceramic component for implantation in living tissue, comprising the steps of:

selecting said ceramic component having a bulk density of at least 6.00 g/cm³ or greater; a total porosity less than 1.0 volume percent; a total open porosity less than 0.1 volume percent; an average grain size equal to or less than 0.6 microns; an initial monoclinic phase content that is equal to or less than 5 percent; a surface finish of 0.05 microns; a mean flexural strength of at least 800 MPa; an elastic modulus of at least 200 GPa; a Vickers hardness of at least 1200 HV;

exposing said ceramic component to steam at 127°C for six hours;

measuring a post-exposure monoclinic phase content in said ceramic component;

determining a difference between said post-exposure monoclinic phase content and said initial monoclinic phase content;

comparing said difference in monoclinic phase content to a preselected allowable limit; and

accepting said ceramic component if said difference in monoclinic phase content is less than said preselected allowable limit.

16. The method for accelerating a qualification test according to claim 15, wherein said step of selecting said ceramic component having a mean flexural strength of at least 800 MPa is selecting a mean strength having greater than a 68% probability of success as determined with a sample population of at least ten samples.

17. The method for accelerating a qualification test according to claim 15, wherein said step of comparing the difference to a preselected allowable limit comprises selecting 2.1% as the allowable limit.